



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

19900 MacArthur Blvd., Ste 300
Irvine, California 92715-2445
Telephone (714) 798-7600

WARNING LETTER

May 2, 1997

WL-22-7

Kenneth A. Darienzo
Chief Executive Officer
Steri-Oss Inc.
22895 Eastpark Drive
Yorba Linda, CA 92887

Dear Mr. Darienzo:

During an inspection of your manufacturing facility conducted between April 7, and April 18, 1997, our investigator determined that your firm manufactures dental implant abutments and dental instruments. These products are devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (Act).

Our investigation revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, or storage are not in conformance with the Good Manufacturing Practice (GMP) for Medical Device Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to control written procedures for finished device inspection to assure that device specifications are met [21 CFR 820.160]. For example, our investigation determined that your firm does not document any finished device testing conducted on the dental implants to assure that device specifications are met prior to release to distribution.
2. Failure to maintain labeling integrity and prevent labeling mix-up [21 CFR 820.120 (a)]. For example, our investigation determined five labeling mix-ups where your firm conducted no failure investigations or inadequate failure investigations, and conclusions.
3. Failure to ensure that device packaging and any device shipping containers are designed and constructed to protect your dental products from alteration or damage during customary conditions of processing, storage, handling and distribution [21 CFR 820.130]. For example, our investigation disclosed that your firm

has had devices returned to your facility because of damage during shipping. Additionally, our investigation determined that your firm has conducted studies of your device packaging and shipping containers which have determined that damage could result to your devices during customary shipping conditions.

4. Failure to conduct investigations, including conclusions and follow-up measures of devices which failed to meet their performance specifications [21 CFR 820.162]. For example, our investigation determined at least five situations where your firm conducted no failure investigations of incidents involving devices which failed to meet their performance specifications.

5. Failure to ensure that device history records for your dental devices demonstrate that these products are manufactured in accordance with their device master record(s) [21 CFR 820.184]. For example, our investigation disclosed that your firm does not document any dimensional measurements as specified in your written procedures.

This letter is not intended to be an all-inclusive list of deficiencies at your facility and/or with your devices. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

We acknowledge that you have submitted to this office a response concerning our investigator's observations noted on the form FDA 483. It appears that the response is adequate, therefore no submissions for premarket clearance will be withheld for GMP reasons.

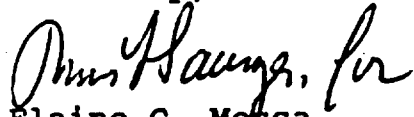
You should take prompt action to correct any manufacturing or quality systems deviations identified by your internal audits. Failure to promptly correct these deviations may be identified in a later comprehensive inspection follow-up inspection, and may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of the letter, of the anticipated date that your facility will be ready for reinspection.

Your reply should be addressed to:

Dannie E. Rowland
Compliance Officer
U.S. Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, California 92715-2445

Sincerely,

A handwritten signature in cursive script, appearing to read "Elaine C. Messa".

Elaine C. Messa
District Director

cc: State Department of Public Health
Environmental Health Services
Att: Chief Food and Drug Branch
601 North 7th Street, MS-357
P.O. Box 942732
Sacramento, CA 94234-7320